IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9214

Bartle, J. March 25, 2014

Sharon K. White ("Ms. White" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she met her burden of proving that her claim

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Larry S. White, Ms. White's spouse, also has submitted a derivative claim for benefits.

was not based, in whole or in part, on any intentional material misrepresentation of fact.[3]

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, David A. Bayne, M.D., F.A.C.C. Based on an echocardiogram dated October 11, 2002, Dr. Bayne attested in Part II of claimant's Green Form that Ms. White suffered from moderate mitral

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

regurgitation and an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $506,076.[4]

In the report of claimant's echocardiogram, Dr. Bayne noted that Ms. White had "mild-to-moderate" mitral regurgitation of 22%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Bayne also stated, "Left atrial size was increased and measured 4.7 [cm] in the parasternal view and 6.1 [cm] in the apical view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. at § IV.B.2.c.(2)(b)ii).

In January, 2004, the Trust forwarded the claim for review by Edward J. Teufel, M.D., one of its auditing cardiologists. In audit, Dr. Teufel concluded that there was a

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4. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors necessary for a Level II claim.

reasonable medical basis for Dr. Bayne's findings of moderate mitral regurgitation and an abnormal left atrial dimension.

Before the Trust issued a determination based on this review, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. After the stay was lifted, we entered Pretrial Order ("PTO") No. 5632, which provided certain claimants, including Ms. White, with the option either to undergo a re-audit of their claims or to elect to stand on the results of their prior audit and proceed pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"). See PTO No. 5632 (Aug. 26, 2005). Ms. White elected not to undergo a re-audit of her claim.

Prior to the Trust's processing of her claim pursuant to the Audit Rules, however, this court approved Court Approved Procedure ("CAP") No. 13, which provided certain claimants, including Ms. White, with the option either to submit their claims to a binding medical review by a participating physician or to opt-out of CAP No. 13 and proceed pursuant to the Audit Rules. See PTO No. 6707 (Nov. 22, 2006). Ms. White elected to opt-out of CAP No. 13.

Thus, pursuant to Rule 5 of the Audit Rules, the Trust undertook "to determine whether there were any intentional material misrepresentations made in connection with the Claim." As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the

performance of echocardiographic studies and the resulting interpretations submitted in support of certain claims. As stated in his April 13, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

> In Ms. White's study, the use of high color gain, excessive depth and a deceased Nyquist setting, the presence of color pixels dominant over anatomy, the selection and planimetry of backflow, and the overmeasurement of the mitral "jet," are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation and jet duration. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating moderate mitral regurgitation. Ms. White has only trivial mitral regurgitation.

Accordingly, notwithstanding Dr. Teufel's findings at audit, the Trust issued a post-audit determination denying the claim based on its conclusion that there was substantial evidence of intentional material misrepresentation of fact in connection with the claim. Pursuant to the Audit Rules, Ms. White contested this adverse determination.[5] In contest, claimant submitted a December 13, 2005 echocardiogram and report performed by her treating physician, Michael S. Schiff, M.D. Although the report

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

states that Ms. White had "mild to moderate mitral insufficiency," it does not specify a percentage as to claimant's level of mitral regurgitation. According to Ms. White, this echocardiogram and report are consistent with Dr. Bayne's original finding of moderate mitral regurgitation.[6]

Ms. White also submitted declarations from Michael S. Mancina, M.D. and Greg Wilson, the echocardiogram technician who performed her October 11, 2002 echocardiogram.[7] In his declaration, Dr. Mancina stated that Dr. Kisslo lacked a fundamental understanding of the Acuson Cypress, the portable echocardiogram machine used to conduct Ms. White's study. Dr. Mancina stated that "[t]he Cypress has had only a limited set of tools to make the image: a single color frequency, a single focal zone, a fixed set of Nyquist (PRF) stops based at set depths, [and] a color gain that goes from 0-30 [cms]," which did not afford the operator control of the color persistence setting in Ms. White's study and any instances of speckling that Dr. Kisslo observed are not indicative of excessive color gain.

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6. Ms. White also suggested that her claim should be paid because the Trust did not timely complete the audit of her claim or otherwise comply with the timing requirements of the Audit Rules. Ms. White, however, failed to demonstrate how she was prejudiced by this delay. As we previously stated, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument without, at a minimum, some showing of prejudice." Mem. in Supp. of PTO No. 6339 at 13 n.10 (May 25, 2006).

7. Mr. Wilson lists the date of the echocardiogram as October 12, 2002. There, however, is no dispute Ms. White's echocardiogram was performed on October 11, 2002.

Dr. Mancina also attested that, at certain depths, the Cypress "can only get 41 or 51 [cm/s] as a maximum PRF (Nyquist) for specific depth however it had [color] filters that compensate for this short coming [sic] to avoid significant expansion of the jet size at Nyquist of 46 compared to 61." In addition to these criticisms, Dr. Mancina objected to Dr. Kisslo's "attempt[ ] to discount this jet as backflow (early systolic) when in fact it is a biphasic (early/late phase) pathologic jet."[8]

Mr. Wilson stated in his declaration that he was trained at Dr. Mancina's office on how to perform "the best possible study and how to avoid creating a false positive or negative study" and that he was never "requested to skew [his] results or deviate from [his] normally accepted practice of performing echocardiograms." In addition, Mr. Wilson noted, "The Nyquist settings used to perform [Ms. White's] study provided a clear and accurate view for the Doctor to review [and] are commonly accepted and used to perform echocardiograms on a daily basis."

The Trust then issued a final post-audit determination, again denying Ms. White's claim. The Trust argued that claimant did not demonstrate a reasonable medical basis for Dr. Bayne's

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8. In addition, Ms. White included an affidavit from Frank R. Miele, in which she contends Mr. Miele "has disputed the determinations made by Dr. Kisslo in his report." The affidavit of Mr. Miele, however, was obtained by another law firm in connection with a different claim and speaks to echocardiography generally. In fact, there is no indication that Mr. Miele even reviewed Dr. Kisslo's report or Ms. White's echocardiogram. Thus, it is not relevant to our disposition of this claim.

representation because Dr. Bayne relied on a manipulated echocardiogram to reach his conclusion. In addition, the Trust maintained that the findings of Dr. Teufel did not provide a reasonable medical basis for Dr. Bayne's representation of moderate mitral regurgitation because Dr. Teufel was not trained to detect the manipulations present in claimant's study.

The Trust also contended that the declaration of Dr. Mancina did not establish a reasonable medical basis for Ms. White's claim. First, the Trust noted that while Dr. Mancina was critical of Dr. Kisslo's recognition of certain trends in the studies Dr. Mancina had performed or supervised, he made no "meaningful attempt to refute the evidence." Second, the Trust asserted that, contrary to Dr. Mancina's characterization, Dr. Kisslo did not state that the jet identified by Dr. Bayne was backflow because it was not holosystolic but because it was of short duration, a claim the Trust says Dr. Mancina did "not address, much less refute." Third, the Trust argued that Dr. Mancina incorrectly claimed that Dr. Kisslo said the color persistence was an adjustable setting in claimant's echocardiogram. The Trust noted, however, that Dr. Mancina did not refute Dr. Kisslo's statement that persistence exaggerated the jet duration. Finally, the Trust rejected Dr. Mancina's suggestion that the Acuson Cypress had color filters that would prevent a jet from becoming exaggerated by an inappropriate Nyquist limit, stating:

> All color Doppler machines, including the Cypress, have color filtration, spatial and otherwise, but none of these will prevent the distortion which results from the use of a Nyquist setting which is too low or color gain which is too high. Spatial color filters "connect the dots" and amplify, rather than reduce, the size of any jet.

Claimant disputed the Trust's final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. White's claim should be paid. On April 15, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7782 (Apr. 15, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response on the Special Master. On June 26, 2008, the Trust informed the Special Master that it intended to rely upon the documents previously submitted and the arguments that it had already raised. The claimant filed a sur-reply on July 21, 2008, which asserts many of the arguments she previously had raised.

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the (continued...)

claims after the Trust and claimant have had the opportunity to develop the show cause record. See Audit Rule 30. The Special Master assigned Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for her claim.[10] Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on

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9. (...continued)
jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

10. Given our disposition with respect to claimant's level of mitral regurgitation, we need not determine whether there is a reasonable medical basis for finding that claimant suffered from one of the necessary complicating factors.

the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant argues that her December 13, 2005 echocardiogram and report and the results of Dr. Teufel's audit provide a reasonable medical basis for her claim. She also contends that Dr. Kisslo's report does not support the Trust's determination because, according to claimant, Dr. Kisslo relied too heavily on examples from "'other Mancina studies.'" Claimant further argues the Trust should be bound by Dr. Teufel's findings as he was trained by the Trust.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

> There was obvious excessive color gain causing color artifact within the myocardial tissue and outside of the heart. In addition, an inappropriately low Nyquist limit of 46 cm per second was noted at a depth of 19.0 cm in the parasternal long axis view. An excessive depth was noted in the parasternal views. However, an appropriate depth was noted in the apical views. In addition, the Nyquist setting was appropriate at 51 cm per second at a depth of 19.0 cm in the apical view. Color pixels dominant over anatomy were obvious in the apical views. In addition, low velocity and non-mitral regurgitant flow was measured as part of the supposed RJA by the sonographer on the study.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that Ms. White had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

> A short central jet of mitral regurgitation was suggested in the parasternal long-axis view. Visually, mild mitral regurgitation was noted in the apical four chamber and two chamber views. I digitized the cardiac cycles in the apical four chamber and two chamber views. In spite of excessive color gain and color pixels dominant over anatomy, I was able to accurately planimeter the RJA in the mid portion of systole. The largest RJA in the apical four chamber view was 3.4 cm2. The largest RJA in the apical two chamber view was 2.4 cm2. I was also able to accurately determine the LAA in this study. The LAA was 31.1 cm2. Therefore, the largest RJA/LAA ratio was 11%. Most of the RJA/LAA ratios were less than 7%. The RJA/LAA ratio never came close to approaching 20%. There were three supposed regurgitant jet areas measured by the sonographer all in the apical four chamber view. These measurements were 3.99 cm2, 6.65 cm2, and 5.75 cm2. These measurements were not representative of mitral regurgitation and included low velocity and non-mitral regurgitant flow. The sonographer measured the LAA to be 30.6 cm2 in the apical four chamber view. This measurement was slightly off axis and inappropriately small. The sonographer's inaccurate RJA determination of 6.65 cm2 and the LAA determination of 30.6 cm2 provides for an RJA/LAA of 22%, which was the same ratio documented by Dr. Bayne in his formal echocardiogram report. I also scrutinized the time frames mentioned by Dr. Mancina in his letter of September 6, 2006. The time frames of 11:45:45-51 documented images of color flow in the parasternal long axis view, a non-qualifying view for mitral regurgitation. The time frame 11:47:54

> demonstrated a supposed RJA of 5.75 cm2 which was inaccurate as documented above.

After reviewing the entire show cause record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Ms. White had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo found that claimant's sonographer improperly "selected, traced, and measured a supposed regurgitant 'jet' that consists of backflow, entrainment, and areas outside of the jet boundary rather than true high velocity sustained regurgitant flow." In addition, Dr. Vigilante determined that the sonographer's measurements of claimant's supposed RJAs "were

not representative of mitral regurgitation and included low velocity and non-mitral regurgitant flow" and that the sonographer's LAA "measurement was slightly off axis and inappropriately small."[11] Finally, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included increased color gain and color pixels dominant over anatomy.

Notwithstanding these deficiencies, Dr. Kisslo determined that claimant's echocardiogram demonstrated, at most, mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's representation that Ms. White had moderate mitral regurgitation.[12] Specifically, Dr. Vigilante explained that "the largest RJA/LAA ratio was 11%" and that "[m]ost of the RJA/LAA ratios were less than 7%."

Claimant's substantive challenge focuses almost exclusively on the proposition that Dr. Kisslo was biased in his review and that he lacked the necessary familiarity with the unique attributes of the Acuson Cypress machine used in her study

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11. Dr. Vigilante noted that these inappropriate measurements resulted in an RJA/LAA ratio of 22%, the same percentage Dr. Bayne noted in his report. Dr. Vigilante also reviewed the two time frames Dr. Mancina contended supported a finding of moderate mitral regurgitation and concluded that the first time frame documented images of color flow in a non-qualifying view and the second was one of the inaccurate tracings of the sonographer.

12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

to render a reliable opinion. Notably, Ms. White makes no such contention against Dr. Vigilante, an independent cardiologist appointed by the court who reached similar conclusions during a separate review. Without identifying some specific error by the Trust's expert and the Technical Advisor, claimant cannot meet her burden of proof in establishing that her claim is payable.[13]

We conclude, based on our review of the entire record, that there is no reasonable medical basis for Dr. Bayne's representation that claimant had moderate mitral regurgitation. Thus, we need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. White's claim.[14]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. White's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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13. We also reject claimant's argument that her December 13, 2005 echocardiogram and report, which states that claimant had "mild to moderate mitral insufficiency," provides a reasonable medical basis for Dr. Bayne's representation, based on claimant's October 11, 2002 echocardiogram, that claimant had moderate mitral regurgitation.

14. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.